REMARKS

Claims 1-25 are pending.

Claims 1-25 were examined and rejected.

Claims 1, 19, 22 and 25 have been amended.

In view of the above amendments and the following remarks, the Examiner is respectfully requested to withdraw the rejections and allow Claims 1-25, the only claims pending in this application after entry of the amendments set-forth herein.

Attached hereto is a marked up version of the changes made to the claims by the current amendment. The attached page is captioned **"Version With Markings to Show Changes Made"**. No new matter has been added.

CLAIM OBJECTION UNDER 35 C.F.R. § 1.75(C)

Claim 25 has been objected to under 35 C.F.R. § 1.75(c) as being in improper form because, the Examiner asserts, it is a multiple dependent claim and thus should refer to other claims in the alternative only. Claim 25 has been amended so that it is not a multiple dependent claim. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The Examiner has rejected Claims 14 and 18 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. The Examiner asserts that Claims 14 and 18 indicate that they contain a "biological buffer" which renders the claims indefinite as it is uncertain what buffers are and are not included within the scope of the term.

The law is clear that "[i]f the claims, read in the light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more." North American Vaccine, Inc. v. American Cyanamid Co. 28 USPQ 2d 1333, 1339 (Fed. Cir. 1993), cert. denied, 114 S. Ct. 1645 (1994).

The Applicants respectfully submit that Claims 14 and 18, when read in light of the specification by one of skill in the art, are not indefinite as the specification precisely describes "biological buffers". This explicit description, reasonably apprises one of skill in the art both of the utilization and scope of the invention. As evidence that the specification precisely describes "biological buffers", the Applicants direct the Examiner's attention at least to page 7, paragraph 22 to page 9, paragraph 26, wherein biological buffers, as well as a dynamic buffering system of the present invention, are described in detail. More specifically, the definition of a biological buffer is described, as well as numerous, specific examples thereof (see paragraph 25). Likewise, the definition of the dynamic buffering system of the present invention, which differs from a biological buffer, is described in detail, as well as specific examples thereof (see paragraphs 22-24). The specification further describes the differences between a biological buffer a conventional buffer, as well as important advantages of employing a dynamic buffering system and omitting a biological buffer (see paragraph 26).

Accordingly, the Applicants respectfully submit that Claims 14 and 18, when read in light of the specification by one skilled in the art, are not indefinite and particularly point out and distinctly claim the subject matter which the Applicant regards as the invention and the Applicants respectfully request that this rejection be withdrawn.

REJECTION UNDER 35 U.S.C. §102(b) OR §103(a)

The Examiner has rejected Claims 1-25 under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under §103(a) as obvious over, Taylor (U.S. Patent No. 5,514,536). The Applicants respectfully submit that the above cited reference does not anticipate Claims 1-25 as amended, nor are claims 1-25 as amended obvious over the cited reference.

Under current case law, a reference does not anticipate a claim unless "all of the elements and limitations of the claim are found within [that]...reference....There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of invention." Scripps Clinic v. Genentech, Inc., 18 USPQ2d 1671, 1672 (Fed. Cir. 1992).

Therefore, in order for a claim to be anticipated by a reference, each and every limitation must be found in that reference. The Applicant respectfully submits that each and every claimed limitation is not found in the cited reference.

As amended, independent Claim 1 and the claims that depend therefrom recite a method that includes two steps: (a) reducing the level of CO_2 in a subject in an amount sufficient to reduce the risk of acidosis/acidemia, and (b) administering a plasma-like solution to the subject.

As described by the Examiner, Taylor teaches a method of administering a blood substitute containing electrolytes, including potassium, sodium, magnesium, calcium, chloride, buffer, including bicarbonate, simple sugar and an oncotic agent, including starch, wherein the subjects are under anesthesia and are hooked up to an oxygenator. However, nowhere are the two steps of the subject invention taught in the disclosure of Taylor. That is, while Taylor teaches anesthetizing an animal, the anesthesia disclosed in Taylor does not reduce the level of CO_2 in an amount sufficient to reduce the risk of acidosis/academia, as evidenced by the fact that Taylor specifically teaches that HCO_3^- and $H_2PO_4^-$ may be included in the purge solution of Taylor to attempt to combat acidosis (Column 12, lines 16-52), and thus acidosis is not managed by the anesthesia. Likewise, the cited reference does not teach that the oxygenator employed by Taylor causes a reduction in CO_2 levels in an amount sufficient to reduce the risk of acidosis/acidemia as evidenced by the disclosure in Taylor that HCO_3^- and $H_2PO_4^-$ may be included in the purge solution of Taylor to attempt to combat acidosis. As such, contrary to the Examiner's assertions, Taylor does not teach that the anesthesia or the oxygenator disclosed in Taylor reduces the level of CO_2 in a subject in an amount sufficient to reduce the risk of acidosis/academia, as shown by the teaching of the use of HCO_3^- and $H_2PO_4^-$ to manage acidosis.

Furthermore, it is important to note that the HCO_3^- and $H_2PO_4^-$components employed by Taylor to combat acidosis are components of the blood substitute solution, more specifically the purge solution, of Taylor (see for example Column 4, lines 20-26). As such, assuming arguendo that the administration of these components to a subject directly or indirectly decreases CO_2 in the subject, Taylor would still fail to each and every claim limitation as the subject claims recite two steps: (1) a step of reducing the level of CO_2 in a subject in an amount sufficient to reduce the risk of acidosis/acidemia, and (2) a step of administering a plasma-like solution to the subject. However Taylor, if one would to argue that the HCO_3^- and $H_2PO_4^-$directly or indirectly reduces CO_2 levels, teaches that any such reduction of CO_2 is

accomplished by the purge solution itself and therefore does not teach the two step method of Claim 1. As such, Taylor does not anticipate Claim 1 and the claims that depend therefrom. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Independent Claim 19 has been amended to recite a system that includes two distinct components: (a) a synthetic plasma-like solution, and (b) a means for reducing the CO_2 level of a subject in an amount sufficient to reduce the risk of acidosis/acidemia.

For reasons analogous to those described above, Taylor does not teach every claim limitation and thus does not anticipate Claim 19 and the claims that depend therefrom. Specifically, if it is suggested that the means for reducing the CO_2 level in a subject is the anesthesia or oxygenator of Taylor, Taylor does not teach that the anesthesia or oxygenator reduces the CO_2 level of the subject in an amount sufficient to reduce the risk of acidosis/academia, as described above. Alternatively, if it is suggested that the HCO_3^- and $H_2PO_4^-$ employed by Taylor to combat acidosis directly or indirectly reduce the level of CO_2 and thus is the means for reducing CO_2, the HCO_3^- and $H_2PO_4^-$ components disclosed in Taylor are included in the blood substitute solution of Taylor and thus do not teach the two component system of the present invention. As such, Taylor does not anticipate Claim 19 and the claims that depend therefrom. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Independent Claim 22, and the claims that depend therefrom, have been amended to recite that the kit includes two distinct components: (a) a synthetic plasma-like solution, and (b) a means for reducing the CO_2 level of a subject in an amount sufficient to reduce the risk of acidosis/acidemia. Accordingly, for reasons analogous to those described above, i.e., because Taylor does not teach a kit that includes both a synthetic plasma-like solution and a means for reducing the CO_2 level of a subject in an amount sufficient to reduce the risk of acidosis/academia, as claimed in Claim 22, Taylor does not anticipate Claim 22 and the claims that depend therefrom. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Furthermore, Taylor does not render Claims 1-25 obvious. The M.P.E.P. at § 2142 teaches that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there

must be a reasonable expectation of success. **Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.**

As described above, Claim 1 as amended recites a method that includes two steps: (a) reducing the level of CO_2 in a subject in an amount sufficient to reduce the risk of acidosis/acidemia, and (b) administering a plasma-like solution to the subject. Nowhere in the disclosure of Taylor is it taught or suggested to (a) decrease the level of CO_2 in a subject in an amount sufficient to reduce the risk of acidosis/acidemia, and (b) administer a plasma-like solution to the subject, as described above. In fact, Taylor teaches away from this two step method of administering a synthetic plasma-like solution to a subject by teaching that HCO_3^- and $H_2PO_4^-$ may be included in the blood substitute solutions themselves. As such, Taylor at best suggests a one step method, instead of the two step method of Claim 1. Accordingly, Taylor does not teach or suggest all the claim limitations of Claim 1 and the claims that depend therefrom and a *prima facie* case of obviousness can not be sustained. Thus, Claim 1 and the claims that depend therefrom are not obvious under 35 U.S.C. §103(a) in view of the above-cited reference and the Applicants respectfully request that this rejection be withdrawn.

In regards to independent Claim 19 and the claims that depend therefrom, as described above, nowhere in the disclosure of Taylor is a system taught or even suggested that includes the two components of the claimed system, namely: (a) a synthetic plasma-like solution, and (b) a means for reducing the CO_2 level of a subject in an amount sufficient to reduce the risk of acidosis/academia. As described above, Taylor at best suggests a single component system where the means for combating acidosis is included in the purge solution itself, while a two component system of a synthetic plasma-like solution and a means for reducing the CO_2 level of a subject in an amount sufficient to reduce the risk of acidosis/academia, is claimed in Claim 1. Thus, Claim 19 and the claims that depend therefrom are not obvious under 35 U.S.C. §103(a) in view of the above-cited reference and the Applicants respectfully request that this rejection be withdrawn.

In regards to Claim 22 and the claims that depend therefrom, as described above, Taylor does not teach a kit having the two components of the claimed kit, namely: (a) a synthetic plasma-like solution, and (b) a means for reducing the CO_2 level of a subject in an amount sufficient to reduce the risk of acidosis/academia. As described above, Taylor at best suggests a single component where the means for combating acidosis is included in the purge solution itself, while a two component kit of a synthetic

plasma-like solution and a means for reducing the CO_2 level of a subject in an amount sufficient to reduce the risk of acidosis/academia is claimed in Claim 22. Thus, Claim 22 and the claims that depend therefrom are not obvious under 35 U.S.C. §103(a) in view of the above-cited reference and the Applicants respectfully request that this rejection be withdrawn.

The Examiner has rejected Claims 1-25 under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under §103(a) as obvious over, Segall et al. (U.S. Patent No. 5,702,880) or Segall et al. (U.S. Patent No. 5,571,801). The Applicants respectfully submit that neither of the above cited references anticipates Claims 1-25 as amended, nor are claims 1-25 as amended obvious over either of the cited references.

As described above, to anticipate a claim, each and every limitation must be found in that reference. The Applicant respectfully submits that each and every claimed limitation is not found in the cited references.

As described above, independent Claim 1 as amended, and the claims that depend therefrom, recite a method that includes two steps: (a) reducing the level of CO_2 in a subject in an amount sufficient to reduce the risk of acidosis/acidemia, and (b) administering a plasma-like solution to the subject.

As the Examiner notes, Segall et al. teach a method of administering a blood substitute. However, neither the '801 patent nor the '880 patent teach the two step method of Claim 1, namely a method of (a) reducing the level of CO_2 in a subject in an amount sufficient to reduce the risk of acidosis/acidemia, and (b) administering a plasma-like solution to the subject.

While the cited references disclose anesthetizing a subject and/or placing a subject on an oxygenator, it is not taught in these references that either results in a reduction of the level of CO_2 in the subject in an amount sufficient to reduce the risk of acidosis/academia. In particular, as evidence that the methods disclosed in the '801 patent does not teach reducing the level of CO_2 in the subject in an amount sufficient to reduce the risk of acidosis/academia, the '801 patent teaches that following the procedure in which the solutions disclosed therein are administered to a subject, sodium bicarbonate was administered as needed to manage acidosis (see Column 19, lines 66-67). In other words, the management of acidosis, as described in the '801 patent, occurs after the procedure has been completed,

in fact it occurs after the incisions are closed (Column 19, lines 65-66) such that acidosis management occurs post-operatively. Likewise, the '880 patent fails to teach a method wherein the level of CO_2 in a subject is reduced in an amount sufficient to reduce the risk of acidosis/acidemia and in fact does not even discuss acidosis/acidemia. As such, both the '801 patent and the '880 patent fail to teach each and every claimed limitation and thus neither cited reference anticipates Claim 1 and the claims that depend therefrom. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

In regards to independent Claim 19 and the claims that depend therefrom, Claim 19 has been amended to recite a system that includes two distinct items: (a) a synthetic plasma-like solution, and (b) a means for reducing the CO_2 level of a subject in an amount sufficient to reduce the risk of acidosis/acidemia.

For reasons analogous to those described above, i.e., both the '801 patent and the '880 patent fail to teach a system that includes means for reducing the CO_2 level of a subject in an amount sufficient to reduce the risk of acidosis/acidemia, neither reference anticipates Claim 19 and the claims that depend therefrom. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

In regards to Claim 22, as described above, independent Claim 22 has been amended to recite that the kit includes a means for reducing the CO_2 level in a subject in an amount sufficient to reduce the risk of acidosis/acidemia. Accordingly, for reasons analogous to those described above, i.e., because neither cited reference teaches a kit that includes (a) a synthetic plasma-like solution, and (b) a means for reducing the CO_2 level of a subject in an amount sufficient to reduce the risk of acidosis/academia, neither the '801 patent nor the '880 patent anticipates Claim 22 and the claims that depend therefrom. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Furthermore, Claims 1-25 are not rendered obvious in view of the '801 patent nor in view of the '880 patent As described above, Claim 1 as amended recites a method that includes two steps: (a) reducing the level of CO_2 in a subject in an amount sufficient to reduce the risk of acidosis/acidemia, and (b) administering a plasma-like solution to the subject. Nowhere in the disclosures of the cited references is it taught or suggested to (a) decrease the level of CO_2 in a subject in an amount sufficient to reduce the risk of acidosis/acidemia, (b) and administer a plasma-like solution to the subject, as described above. In fact, the '801 teaches away from this two step method of reducing the risk of

acidosis/academia by teaching that acidosis may be managed post-procedurally and the '880 patent is not concerned with acidosis management. Accordingly, the cited references do not teach or suggest all the claim limitations of Claim 1 and the claims that depend therefrom and a *prima facie* case of obviousness can not be sustained. Thus, Claim 1 and the claims that depend therefrom are not obvious under 35 U.S.C. §103(a) in view of the above-cited references and the Applicants respectfully request that this rejection be withdrawn.

In regards to independent Claim 19 and the claims that depend therefrom, as described above, nowhere in the disclosure of cited references is a system taught or even suggested that includes the two components of the claimed system, namely: (a) a synthetic plasma-like solution, and (b) a means for reducing the CO_2 level of a subject in an amount sufficient to reduce the risk of acidosis/academia. Thus, Claim 19 and the claims that depend therefrom are not obvious under 35 U.S.C. §103(a) in view of the above-cited references and the Applicants respectfully request that this rejection be withdrawn.

In regards to Claim 22 and the claims that depend therefrom, as described above, neither the '801 patent nor the '880 patent teach or even suggest a kit having the two components of the claimed kit, namely: (a) a synthetic plasma-like solution, and (b) a means for reducing the CO_2 level of a subject in an amount sufficient to reduce the risk of acidosis/academia. Thus, Claim 22 and the claims that depend therefrom are not obvious under 35 U.S.C. §103(a) in view of the above-cited references and the Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

In view of the remarks, this application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issue.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815, reference no. BIOT008.

Respectfully submitted,
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Please amend the claims as follows:

1. (Amended) A method of administering a synthetic plasma-like solution to a subject in need thereof, said method comprising:

(a) reducing the level of CO_2 in said subject in an amount sufficient to reduce the risk of acidosis/acidemia; and

(b) administering said plasma-like solution to said subject~~;~~.

~~wherein said method results in a reduced risk of acidosis/acidemia.~~

19. (Amended) A system for administering a synthetic plasma-like solution to a subject in need thereof, said system comprising:

(a) a synthetic plasma-like solution; and

(b) a means for reducing the CO_2 level of a subject in an amount sufficient to reduce the risk of acidosis/acidemia.

22. (Amended) A kit for administering a synthetic plasma-like solution to a subject in need thereof, said system comprising:

(a) a synthetic plasma-like solution; and

(b) a means for reducing the CO_2 level of a subject in an amount sufficient to reduce the risk of acidosis/acidemia.

25. (Amended) The kit according to Claim 22, wherein said kit further comprises instructions for ~~practicing the method of Claim 1~~ reducing the level of CO_2 in a subject in an amount sufficient to reduce the risk of acidosis/acidemia and administering said plasma-like solution to said subject.